UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

DENISE BURKHART, Plaintiff, v. ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc., GYNECARE, JOHNSON & JOHNSON Defendant.	)	CASE NO. _____

COMPLAINT AND JURY DEMAND

Plaintiff, DENISE BURKHART, by and through her counsel, brings this Complaint as an administrative device to set forth potential claims individual Plaintiff may assert against Defendants in this litigation. Accordingly, Plaintiff alleges as follows:

I. PARTIES

1. Plaintiff DENISE BURKHART ("Plaintiff") is, and was, at all relevant times, a resident of Antioch, Illinois.

2. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson located in Somerville, New Jersey.

3. Defendant, Ethicon Women's Health and Urology is a division of Ethicon, Inc. located in Somerville, New Jersey.

4. Defendant, Gynecare is a division of Ethicon, Inc. located in Somerville, New Jersey.

5. Defendant, Johnson & Johnson is a corporation, and according to its website, the world's largest and most diverse medical devices and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

II. JURISDICTION AND VENUE

6. Venue is proper as Plaintiff was implanted with Defendant's Pelvic Mesh Products and was injured in this district.

7. Defendants conducted substantial business in the State of Illinois and in this District, distributes Pelvic Mesh Products in this District, receives substantial compensation and profits from sales of Pelvic Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District.

8. Defendants conducted business in the State of Illinois through sales representatives conducting business in the State of Illinois and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or selling, either directly or indirectly, and/or through third parties or related entities, Pelvic Mesh Products; thus, there exists a sufficient nexus between Defendant forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in Illinois.

9. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Illinois such that requiring an appearance does not offend traditional notices of fair play and substantial justice.

III. DEFENDANTS' PELVIC MESH PRODUCTS

10. In or about October, 2002, the Defendants began to market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

11. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants' prolene mesh hernia product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

12. In or about September, 2005, the Defendants began to market and sell a product known as Prolift, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift include by reference all variations.

13. In or about May, 2008, the Defendants began to market and sell a product known as Prolift+M, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift+M include by reference all variations.

14. The Defendants market and sell a product known as TVT, for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple variations

including, but not limited to, the TVT, TVT-O, and TVT-S, and all references to the TVT include by reference all variations.

15. The products known as Prolene Mesh, Gynemesh,, Prolift, Prolift+M, and TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' Pelvic Mesh Products or the Pelvic Mesh Products.

16. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, and sold and distributed by the Defendants, at all times relevant herein.

IV. FACTUAL BACKGROUND

17. Plaintiff DENISE BURKHART was implanted with the Gynecare TVT™ mesh ("Product") during surgery performed on April 17, 2006 at Condell Medical Center in Libertyville, Illinois.

18. The Product was implanted in Plaintiff to treat her pelvic organ prolapsed and/or stress urinary incontinence, the use for which the Product was designed, marketed and sold.

19. As a result of having the Product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

20. Defendants' Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical

conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

21. The Defendants have marketed and sold the Defendants' Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, and telephone information lines, offering exaggerated and misleading expectations as to the safety and utility of the Defendants' Pelvic Mesh Products.

22. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff. In a study published based on a multi-center randomized controlled trial in August, 2010 in the Journal of the American College of Obstetricians and Gynecologists, it was concluded that there is a high (15.6%) vaginal mesh erosion rate with the Prolift, "with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs." Numerous studies published in influential medical journals have reached similar conclusions.

23. The Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

24. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Defendants' Pelvic Mesh Products were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into the Plaintiff.

25. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' Pelvic Mesh Products.

26. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' Pelvic Mesh Products; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' Pelvic Mesh Products.

27. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ

prolapse, and similar other conditions have existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

28. The Defendants' Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendants.

29. The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Pelvic Mesh Products, and thus increase the sales of the Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

30. The Pelvic Mesh Products implanted into the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants, and in the condition directed by and expected by the Defendants.

31. The injuries, conditions, and complications suffered due to Defendants' Pelvic Mesh Products include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to Plaintiff' intimate partners.

32. Despite Defendants' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Products, the Defendants have, and continue to manufacture, market, and sell the Products, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to the Defendants' Pelvic Mesh Products, both prior to and after the marketing and sale of the Products.

COUNT I

PRODUCT LIABILITY ACT – FAILURE TO WARN

33. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

34. The Defendants failed to properly and adequately warn and instruct the Plaintiff and their health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants' Pelvic Mesh Products.

35. The Defendants failed to properly and adequately warn and instruct the Plaintiff and their health care providers as to the risks and benefits of the Defendants' Pelvic Mesh Products, given the Plaintiff' conditions and need for information.

36. The Defendants failed to properly and adequately warn and instruct the Plaintiff and their health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

37. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

38. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

39. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct.

WHEREFORE, Plaintiff demands judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT II

STRICT LIABILITY

40. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

41. At the time of Plaintiff' injuries, the Defendants' Pelvic Mesh Products were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiff, and the warnings labels, and instructions were deficient.

42. Plaintiff adopts the *Restatement of Torts (Second)* and/or the *Restatement of Torts (Third)*, bringing strict product liability claims under the common law, *Section 402A of the Restatement of Torts (Second), and/or Restatement of Torts (Third))* against Defendants.

43. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III

NEGLIGENCE

44. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

45. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' Pelvic Mesh Products, and recruitment and training of physicians to implant the Pelvic Mesh Products.

46. Defendants breached their duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the Pelvic Mesh Products.

47. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demandsjudgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV

NEGLIGENCE CLAIMS UNDER THE APPLICABLE LAWS OF CONNECTICUT

48. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

49. Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, labeling, sale and distribution of the Defendants' Pelvic Mesh Products, including a duty to assure that the Products did not cause unreasonable, dangerous side-effects to users.

50. Defendants failed to exercise ordinary care in the design, manufacture, marketing, labeling, sale, and distribution, quality assurance, quality control, and distribution of the Defendants' Pelvic Mesh Products in that Defendants knew or should have known that the Defendants' Pelvic Mesh Products created a high unreasonable risk of harm.

51. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V

COMMON LAW FRAUD

52. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

53. Defendants falsely and fraudulently have represented and continue to represent to the medical and healthcare community, Plaintiff, the FDA, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective.

54. The representations made by Defendants were, in fact, false. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Pelvic Mesh Products.

55. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

56. In representations to Plaintiff and/or to Plaintiff' healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a) That the Defendants' Pelvic Mesh Products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b) That the risk of adverse events with the Defendants' Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

c) The Defendants' Pelvic Mesh Products were not adequately tested;

d) That the limited clinical testing revealed the Defendants' Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e) That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

f) That Defendants were aware of dangers in the Defendants' Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

g) That the Defendants' Pelvic Mesh Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

h) That patients needed to be monitored more regularly than usual while using the Defendants' Pelvic Mesh Products and that in the event the products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;

i) That the Defendants' Pelvic Mesh Products were manufactured negligently;

j) That the Defendants' Pelvic Mesh Products were manufactured defectively;

k) That the Defendants' Pelvic Mesh Products were designed negligently, and designed defectively;

57. Defendants were under a duty to disclose to Plaintiff and their physicians, the defective nature of the Defendants' Pelvic Mesh Products, including, but not limited to, the heightened risks of erosion, failure, and permanent injury.

58. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Defendants' Pelvic Mesh Products.

59. Defendants' concealment and omissions of material fact concerning the safety of the Products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiff' physicians and healthcare providers to purchase, prescribe, and/or dispense the Pelvic Mesh Products; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Defendants' Pelvic Mesh Products.

60. At the time these representations were made by Defendants, and at the time Plaintiff used the Pelvic Mesh Products, Plaintiff were unaware of the falsehood of these representations, and reasonably believed them to be true.

61. Defendants knew and had reason to know that the Defendants' Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Defendants' Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

62. In reliance upon these false representations, Plaintiff were induced to, and did use the Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiff and their physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and

omissions, and that these included material omissions of facts surrounding the use of the Defendants' Pelvic Mesh Products, as described in detail herein.

63. Plaintiff reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the Defendants' Pelvic Mesh Products.

64. Having knowledge based upon Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff' healthcare providers and physicians, that the Defendants' Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

65. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiff' healthcare providers, and the United States Food and Drug Administration ("FDA").

66. The information distributed to the public, the medical community, the FDA, and Plaintiff, by Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Defendants' Pelvic Mesh Products.

67. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Defendants' Pelvic Mesh Products specifically that the Products did not have dangerous and/or serious adverse health safety concerns, and that the Defendants' Pelvic Mesh Products were as safe or safer than other means of treating stress urinary incontinence and/or prolapse.

68. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

69. Defendants chose to over-promote the purported safety, efficacy and benefits of the Defendants' Pelvic Mesh Products instead.

70. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Products; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Defendants' Pelvic Mesh Products.

71. Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Defendants' Pelvic Mesh Products had innovative beneficial properties and did not present serious health risks.

72. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

73. These representations, and others made by Defendants, were made with the intention of deceiving and defrauding Plaintiff, Plaintiff' healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiff, and their respective healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the Defendants' Pelvic Mesh Products and their healthcare professionals to dispense, recommend, or prescribe the Defendants' Pelvic Mesh Products.

74. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Defendants' Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

75. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiff, as well as their healthcare professionals, into a false sense of security, so that Plaintiff and their healthcare providers would rely on Defendants' representations, and Plaintiff would request and purchase the Defendants' Pelvic Mesh Products, and that their healthcare providers would dispense, prescribe, and recommend the Defendants' Pelvic Mesh Products.

76. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Defendants' Pelvic Mesh Products.

77. At the time the representations were made, Plaintiff and their healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Defendants' Pelvic Mesh Products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations

of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

78. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the Defendants' Pelvic Mesh Products, Plaintiff would not have purchased, used, or relied on Defendants' Pelvic Mesh Products.

79. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

80. As a proximate result of the Defendants' conduct Plaintiff have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI

CONSTRUCTIVE FRAUD

81. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

82. Defendants are in a unique position of knowledge concerning the quality, safety and efficacy of the Defendants' Pelvic Mesh Products, which knowledge is not possessed by Plaintiff or their physicians, and Defendants thereby hold a position of superiority over Plaintiff and their physicians.

83. Despite their unique and superior knowledge regarding the defective nature of the Defendants' Pelvic Mesh Products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Defendants' Pelvic Mesh Products, as compared to other products and forms of treatment.

84. For example, scientists in the recent study published in *Obstetrics & Gynecology*, August, 2010, found that the complication rate was so high that the clinical trial was halted early.

100. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the Defendants' Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Products.

85. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiff to prescribe, dispense, recommend and/or purchase the Defendants' Pelvic Mesh Products. Plaintiff and the medical community have relied upon Defendants' representations.

86. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and their medical providers and engaged in constructive fraud in their relationship with Plaintiff and their medical providers. Plaintiff reasonably relied on Defendants' representations.

87. As a proximate result of the Defendants' conduct, Plaintiff have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability,

impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII

NEGLIGENT MISREPRESENTATION

88. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

89. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

90. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

91. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff' physicians, and the medical and healthcare community.

92. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

93. As a proximate result of the Defendants' conduct, Plaintiff have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

94. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

95. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Pelvic Mesh Products to Plaintiff, carelessly and negligently concealing the harmful effects of the Defendants' Pelvic Mesh Products from

Plaintiff, and carelessly and negligently misrepresented the quality, safety and efficacy of the products.

96. Plaintiff were directly impacted by Defendants' carelessness and negligence, in that Plaintiff have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase the Pelvic Mesh Products sold and distributed by Defendants.

97. As a proximate result of the Defendants' conduct, Plaintiff have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX

BREACH OF EXPRESS WARRANTY

98. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

99. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Products.

100. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Products be used in the manner that Plaintiff in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable

quality, that its side effects were minimal and comparable to other pelvic mesh products, and that it was adequately tested and fit for its intended use.

101. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the Pelvic Mesh Products; which is to say that Plaintiff were foreseeable users of the Defendants' Pelvic Mesh Products.

102. Plaintiff and/ or her implanting physicians were at all relevant times in privity with Defendants.

103. The Defendants' Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

104. Defendants breached various express warranties with respect to the Pelvic Mesh Products including the following particulars:

a) Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

1. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Pelvic Mesh Products were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

2. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the products.

105. In reliance upon Defendants' express warranty, Plaintiff were implanted with the Defendants' Pelvic Mesh Products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

106. At the time of making such express warranties, Defendants knew or should have known that the Defendants' Pelvic Mesh Products do not conform to these express representations because the Defendants' Pelvic Mesh Products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Pelvic Mesh Products unreasonably unsafe for their intended purpose.

107. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the Public relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Defendants' Pelvic Mesh Products.

108. Defendants breached their express warranties to Plaintiff in that the Defendants' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

109. Defendants' breaches constitute violations of common law principles and the following statutory provisions: Fla. Stat. Ann. § 672.313.

110. As a proximate result of the Defendants' conduct, Plaintiff have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X

BREACH OF IMPLIED WARRANTY

111. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

112. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Products.

113. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Products be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Defendants impliedly warranted each product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

114. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant the Defendants' Pelvic Mesh Products in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of the Defendants' Pelvic Mesh Products.

115. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

116. The Defendants' Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

117. Defendants breached various implied warranties with respect to the Defendants' Pelvic Mesh Products, including the following particulars:

a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

1. Defendants represented that the Defendants' Pelvic Mesh Products were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Defendants' Pelvic Mesh Products were not as safe or safer than alternatives available on the market; and
2. Defendants represented that the Defendants' Pelvic Mesh Products were more efficacious than alternative pelvic mesh products and procedures and fraudulently concealed information, regarding the true efficacy of the Defendants' Pelvic Mesh Products.

118. In reliance upon Defendants' implied warranty, Plaintiff used the Pelvic Mesh Products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

119. Defendants breached their implied warranty to Plaintiff in that the Defendants' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of Common Law principles and the following statutory provisions: Fla. Stat. Ann. §§ 672.31, *et seq.*

120. As a proximate result of the Defendants' conduct, Plaintiff have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XI

VIOLATION OF CONSUMER PROTECTION LAWS

121. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

122. Plaintiff purchased and used the Defendants' Pelvic Mesh Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

123. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' Pelvic Mesh Products, and would not have incurred related medical costs and injury.

124. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pelvic Mesh Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct

125. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

1. Advertising goods or services with the intent not to sell them as advertised; and,

2. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

126. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Pelvic Mesh Products. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Products.

127. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Products.

128. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Products, and would not have incurred related medical costs.

129. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

130. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

131. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of Illinois' Uniform Deceptive Trade Practices Act.

132. Under the Illinois' Uniform Deceptive Trade Practices Act to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

133. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh Products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

134. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

135. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Products and failed to take any action to cure such defective and dangerous conditions.

136. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

137. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

138. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff have suffered ascertainable losses and damages.

139. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff have sustained economic losses and other damages and are entitled to statutory and compensatory, damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XII

GROSS NEGLIGENCE

140. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

141. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

142. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

143. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

144. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an

amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII

UNJUST ENRICHMENT

145. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

146. Defendants are and at all times were the manufacturers, sellers, and/or suppliers of the Defendants' Pelvic Mesh Products.

147. Plaintiff paid for the Defendants' Pelvic Mesh Products for the purpose of treatment of stress urinary incontinence and/ or pelvic organ prolapse or other similar condition.

148. Defendants have accepted payment by Plaintiff and others on Plaintiff' behalf for the purchase of the Defendants' Pelvic Mesh Products.

149. Plaintiff has not received the safe and effective medical devices for which they paid.

150. It would be inequitable for Defendants to keep this money since Plaintiff did not in fact receive a safe and effective medical device.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages,

together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIII

PUNITIVE DAMAGES

151. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

152. At all times relevant hereto, Defendants knew or should have known that the Defendants' Pelvic Mesh Products were inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

153. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Defendants' Pelvic Mesh Products.

154. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Defendants' Pelvic Mesh Products.

155. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods products and/or procedures and/or treatment.

156. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' Pelvic Mesh Products cause debilitating and potentially lethal side effects

with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same.

157. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk of injuries caused by the Defendants' Pelvic Mesh Products.

158. Notwithstanding the foregoing, Defendants continue to aggressively market the Defendants' Pelvic Mesh Products to consumers, without disclosing the true risk of side effects where there were safer alternatives.

159. Defendants knew of the Defendants' Pelvic Mesh Products defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Defendants' Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Defendants' Pelvic Mesh Products.

160. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Defendants' Pelvic Mesh Products in order to ensure continued and increased sales.

161. Defendants' intentionally reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable them to weigh the true risks of using the Defendants' Pelvic Mesh Products against their benefits.

162. As a direct and proximate result of the foregoing acts and omissions, Plaintiff have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiff are informed and believe and further allege that

Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

163. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages pursuant to Illinois Law.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

i. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

ii. Restitution and disgorgement of profits;

iii. Reasonable attorneys' fees;

iv. The costs of these proceedings;

v. All ascertainable economic damages;

vi. Punitive damages;

vii. Survival damages (if applicable);

viii. Wrongful death damages (if applicable); and

ix. Such other and further relief as this Court deems just and proper.

DATED: March 23, 2012

/s/ Peter J. Flowers
Peter J. Flowers (#06210847)
PJF@Foote-Meyers.com
Foote, Meyers, Mielke & Flowers, LLC.
3 North Second Street, Suite 300
St. Charles, Illinois 60174
Phone: (630) 232-6333

CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2012, I electronically filed the foregoing document with the clerk of the court for the U.S. District Court, Northern District of Illinois, using the electronic case filing system of the Court.

/s/ Peter J. Flowers_____